

REMARKS

Claims 1 to 19 were pending in this application. Claims 1 and 13 have been amended and claims 10 and 15 to 19 have been canceled. Support for the amendments to claim 1 can be found at page 5, line 10, to page 8, line 16. Claims 1 to 9 and 11 to 14 are pending.

The Examiner rejected claims 1 and 15 to 19 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner contends that the recitation of “wherein the vitamin D binding proteins are not removed from the sample” in claim 1 is indefinite.

Applicants respectfully traverse this rejection of the claims. Although Applicants disagree with the Examiner, the claims have been amended to expedite prosecution of this application. Claim 1 now recites that the method comprises an immunoassay in which the vitamin D binding proteins are not removed from the sample before contacting the sample with an antibody. Claims 15 to 19 have been canceled. Accordingly, Applicants respectfully request that the Examiner withdraw this rejection of the claims.

The Examiner rejected claims 1 to 13 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,787,660 B1 (Armbruster et al.) in view of U.S. Patent No. 5,382,530 (Romelli et al.). The Examiner states that Armbruster describes a method for assaying 25-hydroxy-vitamin D in which the vitamin D binding proteins are not removed from the sample (FIG. 6 and column 9, lines 1 to 6) and that Romelli teaches varying the pH of a sample as a means for dissociating vitamins from their respective binding proteins. The Examiner concludes that it would have been obvious to one of skill in the art to use the method for assaying

25-hydroxy-vitamin D as taught by Armbruster with the step of lowering pH as taught by Romelli.

Applicants respectfully traverse this rejection of the claims. Armbruster describes at FIG. 6 and column 9, lines 1 to 6, a competitive protein binding test in which 25-OH-vitamin-D<sub>3</sub>-biotin and 25-OH-vitamin D (from a standard or sample) compete in liquid phase for the binding site of the vitamin D binding protein. Armbruster describes an immunoassay without any lowering of pH. Accordingly, Armbruster does not teach or suggest the claimed invention in which the pH of the sample is lowered to dissociate the 25-hydroxy-vitamin D from vitamin D binding proteins.

Romelli does not remedy this defect of Armbruster. First, there is no suggestion in Armbruster or Romelli to combine these references to arrive at a competitive protein binding test for vitamin D in which the pH of the sample is lowered to dissociate the vitamin D from the vitamin D binding proteins. Second, even if the references are combined, the claimed invention still is not suggested to one of skill in the art. The competitive protein binding test described at column 9, lines 1 to 6, of Armbruster will not function if the pH of the sample is lowered to dissociate the vitamin D from the vitamin D binding proteins.

The competitive protein binding test of Armbruster functions because the labeled vitamin D and the unlabeled vitamin D from a sample compete to bind with the vitamin D binding proteins. If the vitamin D does not bind with the vitamin D binding proteins, nothing meaningful is measured. The combination of Armbruster and Romelli does not suggest to one of skill in the art the claimed

Amendment and Response  
Applicants: James L. Sackrison et al.  
Serial No.: 10/706,567

Attorney Docket: DIA1001US

invention because the combination of Armbruster and Romelli does not result in a functioning assay. Accordingly, Applicants respectfully request that the Examiner withdraw this rejection of the claims.

The Examiner rejected claim 14 under 35 U.S.C. § 103(a) as being unpatentable over Armbruster in view of Romelli, as applied to claims 1, 10 and 13, and further in view of Schroeder et al., 57 Methods Enzymol. 424-445 (1978).

Applicants respectfully traverse this rejection of the claims. Claim 14 depends from claim 1. As noted above in the discussion of the rejection of claims 1 to 13 as unpatentable over Armbruster and Romelli, neither of these documents or their combination teaches or suggests the invention of claim 1. Schroeder does not remedy this deficiency of Armbruster and Romelli. Accordingly, Applicants respectfully request that the Examiner withdraw this rejection of the claims.

The Examiner made rejections of claims 15 and 19; claim 16; and claim 17 over various references. These claims have been cancelled. Accordingly, Applicants respectfully request that the Examiner withdraw this rejection of the claims.

In view of the above amendments and remarks, Applicants respectfully request that the Examiner withdraw the rejections of the claims.

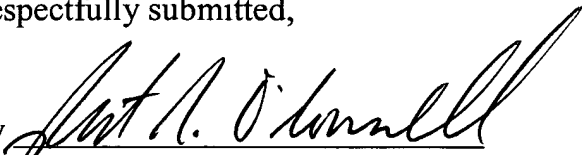
Amendment and Response  
Applicants: James L. Sackrison et al.  
Serial No.: 10/706,567

Attorney Docket: DIA1001US

If any additional fees are due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 16-2312. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our deposit account.

Respectfully submitted,

Date: April 1, 2005

By 

**Customer No. 009561**

Patrick J. O'Connell (33,984)

POPOVICH, WILES &

O'CONNELL, P.A.

650 Third Avenue South, Suite 600

Minneapolis, MN 55402

Telephone: (612) 334-8989

Attorney for Applicants